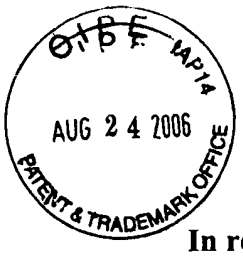
TFW 1648

SAS:dsh 8/15/06 4239-67021-06 566231 E-184-2002/0-US-03

PATENT
Attorney Reference Number 4239-67021-06



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Klinman et al.

Application No. 10/533,634

Filed: April 29, 2005

Confirmation No. 5041

For: METHOD OF PREVENTING INFECTIONS FROM BIOTERRORISM AGENTS WITH IMMUNOSTIMULATORY CPG OLIGONUCLEOTIDES

Examiner: Not yet assigned.

Art Unit: 1648

Attorney Reference No. 4239-67021-06

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Enclosed for filing in the application referenced above are the following:

- ☒ Information Disclosure Statement
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- ☒ The Director is hereby authorized to charge any additional fees that may be required, or credit over-payment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.
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Respectfully submitted,

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cc: Docketing

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INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97(b)(3)

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Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Applicants would like to also bring an interference proceeding to the attention of the Examiner (Proceedings No. 105,171), and pending U.S. Application No. 11/131,672, filed May 17, 2005; U.S. Application No. 09/818,918, filed May 27, 2001; U.S. Application No. 10/068,160, filed February 6, 2002; U.S. Application No. 10/486,755, filed February 12, 2004; U.S. Application No. 10/499,597, filed June 17, 2004; U.S. Application No. 10/679,710, filed October 3, 2003; U.S. Application No. 10/194,035, filed July 12, 2002; U.S. Application No. 09/958,713, filed October 7, 2002; U.S. Application No. 10/194,035, filed July 12, 2002; U.S. Application No. 09/136,138, filed August 18, 1998; U.S. Application No. 10/666,022, filed September 17, 2003.

Copies of United States patents and United States published patent applications do not have to be provided to the Patent Office (37 C.F.R. 1.98(a)(2)(ii)). Copies of unpublished U.S. applications do not have to be provided, as long as the application is available on PAIR, as this requirement of 37 C.F.R. § 1.98(a)(2)(iii) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on October 19, 2004 (1287 OG 163). Applicants will provide copies of such patents or applications upon request.

Applicants filed this Information Disclosure Statement ("IDS") before the mailing date of a first Office action on the merits. As a result, no fee should be required to file this IDS. However, if the Patent Office determines that a fee is required for Applicants to file this IDS, deposit account authority is given on the accompanying transmittal letter.

The filing of this IDS shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. §1.56.

Respectfully submitted,

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Registration No. 43,121

Attorney Docket Number	4239-67021-06
Application Number	10/533,634
Filing Date	April 29, 2005
First Named Inventor	Klinman
Art Unit	1648
Examiner Name	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

U.S. PATENT DOCUMENTS

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Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		6,194,388	2/27/2001	Krieg, et al.
		6,207,646	3/27/2001	Krieg, et al.
		6,214,806	4/10/2001	Krieg, et al.
		6,218,371	4/17/2001	Krieg, et al.
		6,239,116	5/29/2001	Krieg, et al.
		6,339,068	1/15/2002	Krieg, et al.
		6,406,705	6/18/2002	Davis, et al.
		6,423,539	7/23/2002	Fong, et al.
		6,428,788	8/6/2002	Debinski, et al.
		6,429,199	8/6/2002	Krieg, et al.
		6,498,148	12/24/2002	Raz
		6,514,948	2/4/2003	Raz, et al.
		6,534,062	3/18/2003	Krieg, et al.
		6,552,006	4/22/2003	Raz, et al.
		6,562,798	5/13/2003	Schwartz
		6,589,940	7/8/2003	Raz, et al.

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Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		6,610,661	8/26/2003	Carson, et al.
		6,613,751	9/2/2003	Raz, et al.
		6,653,292	11/25/2003	Krieg, et al.
		2001-0034330	10/25/2001	Kensil
		2001-0036462	11/1/2001	Fong, et al.
		2001-0044416	11/22/2001	McCluskie, et al.
		2001-0046967	11/29/2001	Van Nest
		2002-0006403	1/17/2002	Yu, et al.
		2002-0028784	3/7/2002	Van Nest
		2002-0042383	4/11/2002	Yew, et al.
		2002-0042387	4/11/2002	Raz, et al.
		2002-0055477	5/9/2002	Van Nest, et al.
		2002-0064515	5/30/2002	Krieg, et al.
		2002-0065236	5/30/2002	Yew, et al.
		2002-0086295	7/4/2002	Raz, et al.
		2002-0086839	7/4/2002	Raz, et al.

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Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		2002-0090724	7/11/2002	Taylor, et al.
		2002-0091095	7/11/2002	Phillips, et al.
		2002-0091097	7/11/2002	Bratzler, et al.

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		EPO	EP 1 198 249	4/24/2002	
		WIPO	WO 92/18522	10/29/1992	
		WIPO	WO 94/19945	9/15/1994	
		WIPO	WO 97/28259	8/7/1997	
		WIPO	WO 99/11275	3/11/1999	
		WIPO	WO 00/06588	2/0/2000	
		WIPO	WO 00/20039	4/13/2000	
		WIPO	WO 00/21556	4/20/2000	
		WIPO	WO 00/61151	10/19/2000	

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FOREIGN PATENT DOCUMENTS

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		WIPO	WO 00/62787	10/26/2000	
		WIPO	WO 00/67023	11/9/2000	
		WIPO	WO 01/00232	1/4/2001	
		WIPO	WO 01/02007	1/11/2001	
		WIPO	WO 01/12223	2/22/2001	
		WIPO	WO 01/22990	4/5/2001	
		WIPO	WO 01/51500	7/19/2001	
		WIPO	WO 01/55341	8/2/2001	
		WIPO	WO 01/68077	9/20/2001	
		WIPO	WO 01/68103	9/20/2001	
		WIPO	WO 01/68116	9/20/2001	
		WIPO	WO 01/68117	9/20/2001	

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Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
		ANFOSSI, et al., "An oligomer complementary to c-myb-encoded mRNA inhibits proliferation of human myeloid leukemia cell lines". Proc. Natl. Acad. Sci. USA 86:3379-3383 (1989).
		BAUER, et al., "Bacterial CpG-DNA Triggers Activation and Maturation of Human CD11c-, CD123+ Dendritic Cells". J. Immunol. 166:5000-5007 (2001).
		BENIMETSKAYA, et al., "Formation of a G-tetrad and higher order structures correlates with biological activity of the RelA (NF-kBp65) 'antisense' oligodeoxynucleotide". Nucleic Acids Research 25(13):2648-2656 (1997).
		BOGGS, et al., "Characterization and modulation of immune stimulation by modified oligonucleotides". Antisense Nucl. Acid Drug Dev. 7(5):461-471 (1997).
		BRANDA, et al., "Amplification of antibody production by phosphorothioate oligodeoxynucleotides". J. Lab Clin. Med. 128(3):329-338 (1996).
		CHU, et al., "CpG oligodeoxynucleotides act as adjuvants that switch on T helper 1 (Th1) immunity". J. Exp. Med. 186(10):1623-1631 (1997).
		DEML, et al., "Immunostimulatory CpG motifs trigger a T Helper-1 immune response to Human Immunodeficiency Virus Type-1 (HIV-1) gp160 envelope protein". Clin. Chem. Lab. Med. 37(3):199-204 (1999).
		GAO, et al., "Phosphorothioate oligonucleotides are inhibitors of human DNA polymerases and Rnase H: Implications for antisense technology". Mol. Pharmacol. 41:223-229 (1992).
		GURSEL, et al., "Differential and Competitive Activation of Human Immune Cells by Distinct Classes of CpG Oligodeoxynucleotide". J. Leuko. Biol. 71:813-820 (2002).
		HALPERN, et al., "Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha". Cell Immunol. 167(1):72-78 (1996).
		ISHIBASHI, et al., "Sp1 Decoy Transfected to Carcinoma Cells Suppresses the Expression of Vascular Endothelial Growth Factor, Transforming Growth Factor β, and Tissue Factor and Also Cell Growth and Invasion Activities". Cancer Research 60:6531-6536 (2000).
		IVERSEN, et al., "Pharmacokinetics of an antisense phosphorothioate oigodeoxynucleotide against rev from human immunodeficiency virus type 1 in the adult male rat following single inections and continuous infusion". Antisense Res. Dev. 4:43-52 (1994).
		JILEK, et al., "Antigen-Independent Suppression of the Allergic Immune Response to Bee Venom Phospholipase A2 by DNA Vaccination in CBA/J Mice". J. Immunol. 166:3612-3621 (2001).
		KADOWAKI, et al., "Distinct CpG DNA and Polyinosinic-Polycytidylic Acid Double Stranded RNA, Respectively, Stimulate CD11c- Type 2 Dendritic Cell Precursoes and CD11c+ Dendritic cells to Produce Type I IFN". J. Immunol. 166:2291-2295 (2001).
		KLINMAN, et al., "Activation of the innate immune system by CpG oligodeoxynucleotides: immunoprotective activity and safety". Springer Semin. Immunopathol. 22:173-183 (2000).
		KRIEG, et al., "CpG motifs in bacterial DNA and their immune effect". Annu. Rev. Immunol. 20:709-760 (2002).

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		KRIEG, et al., "Brief Communication: Oligodeoxynucleotide Modifications Determine the Magnitude of B-Cell Stimulation by CpG Motifs". Antisense & Nucleic Acid Drug Development 6:133-139 (1996).
		KRIEG, et al., "Leukocyte stimulation by oligodeoxynucleotides". Applied Antisense Oligonucleotide Tech. (BOOK):431-448 (1998).
		KRIEG, et al., "CpG DNA: A pathogenic factor in systemic lupus erythematosus?". J. Clin. Immunol. 15(6):284-292 (1995).
		KRIEG, et al., "A role for endogenous retroviral sequences in the regulation of lymphocyte activation". J. Immunol. 143(8):2448-2451 (1989).
		KRIEG, et al., "CpG motifs in bacterial DNA trigger direct B-cell activation". Nature 374:546-549 (1995).
		KRUG, et al., "Identification of CpG Oligonucleotide Sequences with High Induction of IFN-α/β in Plasmacytoid Dendritic Cells". Eur. J. Immunol. 31:2154-2163 (2001).
		KRUG, et al., "Toll-like Receptor Expression Reveals CpG DNA as a Unigue Microbial Stimulus for Plasmacytoid Dendritic Cells Which Synergizes With CD40 Ligand to Induce High Amounts of IL-12". Eur. J. Immunol. 31:3026-3037 (2001).
		KURAMOTO, et al., "Oligonucleotide sequences required for natural killer cell activation". Jpn. J. Cancer Res. 83:1128-1131 (1992).
		LANG, et al., "Guanosine-rich oligodeoxynucleotides induce proliferation of macrophage progenitors in cultures of murine bone marrow cells". Eur. J. Immunol. 29:3496-3506 (1999).
		LAPATSCHEK, et al., "Activation of Macrophages and B Lymphocytes by an Oligodeoxynucleotide Derived from an Acutely Pathogenic Simian Immunodeficiency Virus". Antisense Nucleic Acid Drug Dev. 8(5):357-370 (1998).
		MALTESE, et al., "Sequence context of antisense RelA/NF-kB phohphorothioates determines specificity". Nucleic Acids Research 23(7):1146-1151 (1995).
		MANZEL, et al., "Lack of Immune Stimulation by Immobilized CpG-oligonucletide". Antisense & Nucleic Acid Drug Development 9(5):459-464 (1999).
		MATSON, et al., "Nonspecific suppression of [3H]thymidine incorporation by control oligonucleotides". Antisense Res. Dev. 2(4):325-330 (1992).
		MCINTYRE, et al., "A sense phosphorothioate oligonucleotide directed to the initiation codon of transcription factor NF-kappa B p65 causes sequence-specific immune stimulation". Antisense Res. Dev. 3(4):309-322 (1993).
		PISETSKY, "Immunological consequences of nucleic acid therapy". Antisense Res. Dev. 5:219-225 (1995).
		PRASAD, et al., "Oligonucleotides Tethered to a Short Polyguanylic Acid Stretch are Targeted to Macrophages: Enhanced Antiviral Activity of a Vesicular Stomatitis Virus-Specific Antisense Oligonucleotide". Antimicrobial Agents and Chemotherapy 43(11):2689-2696 (Nov. 1999).
		RAZ, et al., "Intradermal gene immunization: the possible role of DNA uptake in the induction of cellular immunity to viruses". Proc. Natl. Acad. Sci. USA 91:9519-9523 (1994).
		ROMAN, et al., "Immunostimulatory DNA sequences function as T helper-1-promoting aduvants". Nature Med. 3(8):849-854 (1997).

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		SCHWARTZ, et al., "CpG motifs in bacterial DNA cause inflammation in the lower respiratory tract". J. Clin. Invest. 100(1):68-73 (1997).
		STACEY, et al., "Immunostimulatory DNA as an adjuvant in vaccination against Leishmania major". Infect. Immun. 67:3719-3726 (1999).
		TOKUNAGA, et al., "A synthetic single-stranded DNA, poly(dG, dC), induces interferon-α/β and -γ, augments natural killer activity and suppresses tumor growth". Jpn. J. Cancer Res. 79:682-686 (1988).
		TOKUNAGA, et al., "Synthetic oligonucleotides with particular base sequences from the cDNA encoding proteins of Mycobacterium bovis BCG induce interferons and activate natural killer cells". Microbiol. Immunol. 36(1):55-66 (1992).
		VERTHELYI, et al., "Human Peripheral Blood Cells Differentially Recognize and Respond to Two Distinct CpG Motifs". J. Immunol. 166:2372-2377 (2001).
		VERTHELYI, et al., "CpG Oligodeoxynucleotides as Vaccine Adjuvants in Primates". J. Immunol. 168:1659-1663 (2002).
		WEINER, et al., "Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization". Proc. Natl. Acad. Sci. USA 94:10833-10837 (1997).
		YAMAMOTO, et al., "Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length". Antisense Res. Dev. 4:119-123 (1994).
		YAMAMOTO, "Unique palindromic sequences in synthetic oligonucleotides are required to induce inf and augment INF-mediated natural killer activity". J. Immunol. 148(12):4072-4076 (1992).
		YAMAMOTO, et al., "Synthetic oligonucleotides with certain palindromes stimulate interferon production of human peripheral blood lymphocytes in vitro". Jpn. J. Cancer Res. 85:775-779 (1994).
		YAMAMOTO, et al., "Mode of action of oligonucleotide fraction extracted from Mycobacterium bovis BeG". Kekkaku 69(9):29-32 (1994).
		YAMAMOTO, et al., "Lipofection of synthetic oligodeoxyribonucleotide having a palindromic sequence AACGTT to murine splenocytes enhances interferon production and natural killer activity". Microbiol. Immunol. 38(10):831-836 (1994).
		YASWEN, et al., "Effects of Sequence of Thioated Oligonucleotides on Cultured Human Mammary Epithelial Cells". Antisense Research and Development 3:67-77 (1993).
		YI, et al., "IFN-γ promotes IL-6 and 1gM secretion in response to CpG motifs in bacterial DNA and oligonucleotides". J. Immunol. 156:558-564 (1996).
		ZELPHATI, et al., "Inhibition of HIV-1 Replication in Cultured Cells with Antisense Oligonucleotides Encapsulated in Immunoliposomes". Antisense Res. Dev. 3:323 (1993).
		Decision of Interference No. 105,171, The Regents of California *verus* University of Iowa, Coley Pharmaceutical Group, Inc. and The United States of America. July 17, 2006.

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